

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of:) FDA DOCKET: 00N-1571
) DATE: May 20,2002
Enrofloxacin for Poultry: Withdrawal)
of Approval of Bayer Corporation's)
New Animal Drug Application)
(NADA) 140-828 (Baytril))
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Center for Veterinary Medicine's Motion for Leave to Correct the Record

Pursuant to 21 C.F.R. 12.70, the Center for Veterinary Medicine respectfully requests permission to correct its document submission under 21 C.F.R. § 12.85.

The Center for Veterinary Medicine is preparing redacted versions of these documents now, that will be served on the Judge, the parties and submitted for the record as soon as possible, if the Judge so permits by Order.

Because of potential confidentiality concerns, the Center requests the Administrative Law Judge to direct the Dockets Management Branch not to permit access to or copying of Exhibits G-140, G-341, G-559, G-682, G-812, G-837, G-872, G-916 and G-937 until the Judge has ruled on this Motion.

Specifically, the Center requests permission to:

1. Correct Exhibit G-62. The existing exhibit contains two separate documents. The correction would separate the two documents into G-62, a two-page document,

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and a new G-62a, a 37-page document. The index would be corrected to reflect this change.

2. Withdraw Exhibit G-140. This document reflects the Center's internal deliberative process and should not have been placed on the docket. The Center requests that the Judge preclude the use of this document at hearing. The index would be corrected to reflect this change, by indicating that Exhibit G-140 has been withdrawn.
3. Replace Exhibit G-208 with a larger, more legible, copy of the document. CVM is attempting to obtain a better quality copy from the author.
4. Add pages 12-14, 62-72, and 124-132 to Exhibit G-415. These pages of a book appear to contain information related to the issues of the hearing and should have been included in the original submission.
5. Withdraw Exhibit G-341. Exhibit G-341 contains information obtained from a foreign government and CVM is investigating whether that information was obtained under a signed confidentiality agreement. A redacted version will replace the filed copy and will be provided to the public docket, the participants and the Administrative Law Judge. The Center requests that the Judge order all participants to turn over all copies of the unredacted documents to CVM's counsel, to preclude further distribution of this document and to preclude the use of the unredacted document at hearing. If CVM determines that it is not bound by a confidentiality agreement with respect to Exhibit G-341, the Center will re-submit the unredacted copy to the public docket and provide notice thereof to the participants and the Administrative Law Judge.
6. Replace page 82 of Exhibit G-444, because of a copying error.
7. Withdraw Exhibit G-559. The Center is concerned that this document may contain commercial confidential information within the meaning of 21 C.F.R. §20.61(b), 21 C.F.R. 5514.11 and/or 18 U.S.C. 51905 and should not have been placed on the public docket. The document was submitted in properly redacted format on May 10, 2002. The Center requests that the Judge order all participants to turn over all unredacted copies of this document to CVM's counsel, to preclude further distribution of this document and to preclude the use of the unredacted document at hearing. The index would be corrected to reflect this change.
8. Withdraw Exhibit G-682 and replace it with a redacted copy. The Center is concerned that this document may contain commercial confidential information within the meaning of 21 C.F.R. §20.61(b), 21 C.F.R. 5514.11 and/or 18 U.S.C. § 1905 and should not have been placed on the public docket. The Center requests that the Judge order all participants to turn over all unredacted copies of this document to CVM's counsel, to preclude further distribution of this document and to preclude the use of the unredacted document at hearing. CVM will provide a

redacted version of Exhibit G-682 to the public docket and a separate redacted copy to Bayer that redacts potentially commercial confidential information related to a different sponsor. The Administrative Law Judge was properly provided with an unredacted copy. The submission under 21 C.F.R. 512.85 would be corrected by replacing existing Exhibit G-682 with a redacted version, creating a separately redacted version for Bayer, and adding the document that is the current Exhibit G-682 to the Confidential Docket. The index would be corrected to reflect these changes.

9. Correct the pagination error in Exhibit G-691 (page 5 was identified as page 45) and replace Exhibit G-962 with a complete copy of that exhibit (a page was missing and the document had a page numbering error).
10. Withdraw Exhibits G-812 and G-837 from the public docket and replace them with redacted copies of these documents. The Center is concerned that Exhibits G-812 and G-837 may contain commercial confidential information within the meaning of 21 C.F.R. §20.61(b), 21 C.F.R. 5514.11 and/or 18 U.S.C. §1905 and should not have been placed on the public docket. The Center requests that the Judge order all participants to turn over all copies of these unredacted documents to CVM's counsel, to preclude further distribution of this document and to preclude the use of these unredacted documents at hearing. The Administrative Law Judge was properly provided unredacted copies of G-812 and G-837. The submission under 21 C.F.R. 512.85 would be corrected to reflect this change by replacing Exhibits G-812 and G-837 with redacted versions of these documents and by adding Exhibits G-812 and G-837 to the Confidential Docket. The index would be corrected to reflect these changes.
11. Correct the Index with respect to Exhibit G-832. The index correctly attributes this letter to its author, G. Holder, but should also reflect that this letter was written by this person in his capacity as the chairman of the Drugs Therapeutics Committee of the American Association of Avian Pathologists. The index would be revised to reflect this correction.
12. Withdraw Exhibit G-872 from the public docket and replace it with a redacted copy. The Center is concerned that this document may contain commercial confidential information within the meaning of 21 C.F.R. 520.61(b), 21 C.F.R. 5514.11 and/or 18 U.S.C. §1905 and should not have been placed on the public docket. The Center requests that the Judge order all participants to turn over all copies of this unredacted document to CVM's counsel, to preclude further distribution of this document and to preclude the use of this unredacted document at hearing. The Administrative Law Judge was properly provided an unredacted copy of Exhibit G-872. The submission under 21 C.F.R. 512.85 would be corrected by replacing existing G-872 with a redacted version and adding G-872 to the Confidential Docket. The index would be corrected to reflect these changes.

13. Withdraw Exhibit G-916 from the public docket and replace it with a redacted version. Exhibit G-916 contains information obtained from another U.S. government agency under a signed confidentiality agreement. The document was redacted but the unredacted version was inadvertently filed with the Center's original document submission pursuant to 21 C.F.R. §12.85. A redacted version will replace the filed copy and will be provided to the public docket, the participants and the Administrative Law Judge. The Center requests that the Judge order all participants to turn over all copies of the unredacted documents to CVM's counsel, to preclude further distribution of this document and to preclude the use of the unredacted document at hearing
14. Replace Exhibit G-876 with a complete document. The current exhibit has page 222 missing from the document.
15. Withdraw Exhibit G-937 and replace it with a redacted copy. The Center is concerned that this document may contain commercial confidential information within the meaning of 21 C.F.R. §20.61(b), 21 C.F.R. 9514.11 and/or 18 U.S.C. §1905 and should not have been placed on the public docket. The Center requests that the Judge order all participants to turn over all copies of this unredacted document to CVM's counsel, to preclude further distribution of this document and to preclude the use of this unredacted document at hearing. The submission under 21 C.F.R. §12.85 would be corrected by placing a redacted copy of Exhibit G-937 on the public docket and by placing the current Exhibit G-937 on the Confidential Docket. The index would be changed to reflect these changes.

Respectfully submitted this 20th day of May, 2002, by:


Nadine Steinberg
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane
Rockville, MD 20857
(301) 827-5050

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BEFORE THE FOOD AND DRUG ADMINISTRATION
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Order

By Motion dated May 20, 2002, the Center for Veterinary Medicine has requested permission to correct its document submission pursuant to 21 C.F.R. §12.85. The Dockets Management Branch is ORDERED to not release or permit access or copying of Exhibits G-140, G-341, G-559, G-682, G-812, G-837, G-872, G-916, and G-937 until the Center's Motion has been ruled upon.

Dated this ____ day of May, 2002.

Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Rm. 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

Telephone: (301) 827-7120
FAX: (301) 594-6800

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Order

By Motion dated May 20, 2002, the Center for Veterinary Medicine has requested permission to correct its document submission pursuant to 21 C.F.R. §12.85. The Center's Motion is **HEREBY GRANTED**.

It is **ORDERED** that the exhibits listed in the Center's Motion be corrected, modified, redacted, withdrawn and/or replaced, as described in the Center's Motion.

It is **FURTHER ORDERED** that all Persons having copies of the original Exhibits G-341, G-559, G-682, G-812, G-837, G-916, G-872 and G-937 return the original and any copies of these documents to CVM's counsel within 3 days from this Order.

It is also **FURTHER ORDERED** that no Participant shall be permitted to introduce the existing Exhibit G-140, which will be withdrawn from the public docket.

Dated this ___ day of May, 2002.

Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Rm. 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 827-7120
FAX: (301) 594-6800

CERTIFICATE OF SERVICE

I hereby certify that an original and two copies of the foregoing Center for Veterinary Medicine's Motion to Correct the Record was hand delivered this 20th day of May, 2002, to:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

and

The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that the foregoing Motion was e-mailed and also mailed, postage prepaid, this 20th day of May, 2002, to:

Robert B. Nicholas (rnicholas@mwe.com)
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

and

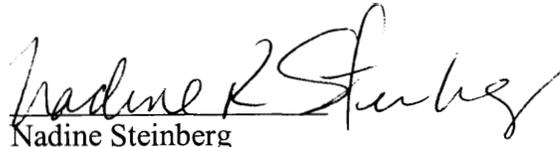
Kent D. McClure (KmcClure@ahi.org)
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

I also certify that the foregoing Motion was e-mailed, this 20th day of May, 2002,
to:

Judge Daniel Davidson (ddavidso@oc.fda.gov)
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3

5600 Fishers Lane
Rockville, MD 20857

Dated: 5/20/02

A handwritten signature in black ink, appearing to read "Nadine R Steinberg". The signature is written in a cursive style with a horizontal line drawn across the middle of the letters.

Nadine Steinberg
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050